S. HRG. 109–815

ALTERNATIVE PLURIPOTENT STEM CELL THERAPIES ENHANCEMENT ACT (S. 2754)

HEARING

BEFORE A

SUBCOMMITTEE OF THE

COMMITTEE ON APPROPRIATIONS

UNITED STATES SENATE

ONE HUNDRED NINTH CONGRESS

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ALTERNATIVE PLURIPOTENT STEM CELL THERAPIES ENHANCEMENT ACT (S. 2754)

THURSDAY, JUNE 27, 2006

U.S. SENATE,
SUBCOMMITTEE ON LABOR, HEALTH AND HUMAN SERVICES, EDUCATION, AND RELATED AGENCIES,
COMMITTEE ON APPROPRIATIONS,
Washington, DC.

The subcommittee met at 9:05 a.m., in room SD–192, Dirksen Senate Office Building, Hon. Arlen Specter (chairman) presiding.

Present: Senators Specter, Stevens, Harkin, and Durbin.

Also present: Senator Santorum.

OPENING STATEMENT OF SENATOR ARLEN SPECTER

Senator SPECTER. Good morning, ladies and gentlemen. The Appropriations Subcommittee on Labor, Health and Human Services, Education, and Related Agencies will now proceed.

We welcome our distinguished colleague, Senator Rick Santorum, who has demonstrated an ingenious approach to the stem cell issue, leading to the introduction of legislation denominated as S. 2754, which I have cosponsored, known as the Santorum-Specter bill.

This subcommittee is now holding its 18th hearing on the issue of stem cell research. When stem cell research was broached back in November 1998, within 10 days this subcommittee undertook its first hearing.

The legislation which we'll be considering today proceeds with the innovative idea of having stem cell research without dealing with the embryo, and it is one where people with different views on underlying philosophical questions can come together. As I have emphasized in the past, this does not mean that I am abandoning my interest in embryonic stem cell research, which Senator Harkin and I have been sponsoring for a long while, which has been passed by the House of Representatives, worth noting that some 50 Republicans joined in passing that legislation.

We're operating under some time constraints today, or at least I am, because the Judiciary Committee has a hearing which has been deferred until 10 o'clock. But I think with the four witnesses we have, we have a reasonably good chance of concluding before 10 o'clock, and in the event we do not, I will yield to Senator Harkin to finish up the hearing. Senator Santorum has been invited to join the panel to question witnesses on the second panel.

It is also worth noting that we had invited Dr. Edmund Pellegrino, chairman of the President's Council on Bioethics, to appear this morning, and he declined to come forward.

Senator Santorum is well known to us all, elected to the House of Representatives in 1990, beat an entrenched incumbent in Pittsburgh, going door-to-door; won an upset victory in 1994, and reelected in the year 2000; holds the number three leadership position in the Republican Caucus; and is well known for a wide body of legislative achievements, and we're hopeful this will be the next in line.

Senator Santorum, we welcome you here, look forward to your comments, and we'll not run the time clock on you.

STATEMENT OF SENATOR RICK SANTORUM

Senator SANTORUM. Thank you very much, Mr. Chairman. Senator Harkin, thank you also for the opportunity to come here and also the opportunity to stay and listen to the testimony.

I want to thank you, Mr. Chairman, for the extensive amount of work that you have done, and that both of you have done on this issue here in this subcommittee. I want to thank you also, Mr. Chairman, for your willingness to work with me over the past year in developing S. 2754, the Alternative Pluripotent Stem Cell Therapies Enhancement Act, which you described in your opening remarks I think aptly, which is a chance to try to take people who are I think of good conscience and of goodwill, who come out with a difference, on opposite sides of the issue of the Specter-Harkin bill, but still believe that we need to pursue scientific research, and do believe that pluripotent cells offer some potential hope for therapies that could enhance our health here in this country and advance medical science here in this country.

We felt that there was a common ground to be able to find, that we could develop pluripotent cells without the destruction of the embryo, and we've worked together over the past year. We've come forward with this piece of legislation, and I'm very pleased that today you are inviting some very distinguished witnesses to discuss this piece of legislation, and I am looking forward to hearing from the scientists and from the ethicists and having an opportunity to question them.

So I will keep my remarks brief, in that I delayed your hearing. I apologize for that. But this whole effort came about as a result of the President's Council on Bioethics white paper that they issued, where they reviewed four techniques where embryonic-like stem cells were derived without creating or harming a human embryo. That sparked an interest I think in many of us, that there may be a way for us to develop these embryonic-like cells or pluripotent cells and avoid some of the ethical problems that the President, myself, and many others here in Washington and around the country have with respect to embryonic stem cell research.

So I am excited that we are going to have this discussion. I suspect that the legislation that we're discussing here today, S. 2754, will be part of the debate here on the floor of the U.S. Senate when we bring up the Specter-Harkin bill, that this will be another piece of legislation that will be offered with maybe one or two other bills.

I think it's an important discussion to have. It's not the full step that you or Senator Harkin would like to see done, and certainly a majority probably in the Senate, as well as you mentioned a majority in the House would like, but I think it is a very good, solid step in the direction of scientific research. It opens up doors that may not have some of the ethical concerns, moral concerns, that many have with the original piece of legislation.

PREPARED STATEMENT

With that, Mr. Chairman, I'll conclude my remarks, and thank you again for having this hearing. I would like if my full statement could be made a part of the record.

Senator SPECTER. Without objection, your full statement will be made a part of the record.

[The statement follows:]

PREPARED STATEMENT OF SENATOR RICK SANTORUM

EXAMINING THE POTENTIAL IMPACT OF S. 2754, THE ALTERNATIVE PLURIPOTENT STEM CELL THERAPIES ENHANCEMENT ACT

Mr. Chairman, I would like to thank you for holding this hearing on this important legislation. I would especially like to thank you for your assistance and work with me in drafting and introducing this legislation. Your work on this is greatly appreciated.

This hearing is an opportunity to present some ideas in an area where there has been a lot of heat and concern in recent years. There has been a lot of division here in the United States Senate about the ethical questions, the moral questions, and the scientific questions related to embryonic stem cell research. People of good conscience have lined up and have found themselves on the opposite sides of issues as those that have traditionally been their allies. I have worked with Senator Specter and several others to see if we can move forward in this area of stem cell research, embryonic or pluripotent stem cell research. We seek to move forward in a way that is both moral and ethical by everyone's judgment while also making significant advances from the scientific research perspective. This legislation is a commonsense compromise that deserves wide support.

I am very pleased that you have invited the distinguished witnesses that are here with us today. I am hopeful that when the issue of stem cell research is taken up by the Senate, this legislation will be part of the discussion.

While there will obviously be much discussion and debate on the original proposal put forward by Senator Specter and Senator Hatch, we should also discuss the alternatives, like this bill, that may be acceptable not only here in the United States Senate, but also in the House and very importantly, at the White House. That support is crucial if such legislation is going to result in increased research and, most importantly, in treatments for patients.

Last year, the President's Council on Bioethics issued a White Paper reviewing four proposed techniques of deriving embryonic stem cells without creating, harming, or destroying an embryo. Since this report was issued, there have been other proposed techniques as well as studies indicating that there may be alternative sources of these valuable cells that have the potential to differentiate into all, or almost all, of the cell types in the body.

I believe that by having pursued the direction taken by the President's Council on Bioethics, we have written language that can accelerate and focus research on areas that are both very promising from a scientific point of view as well as acceptable from a moral and ethical point of view.

I am hopeful that the benefits of this research will be seen in the short term therapeutic use of pluripotent stem cells, as we see that there are a number of companies that are pursuing therapies using stem cells and trying to develop pluripotent cells for clinical treatment and for commercial purposes. This research is also important in the long term as we consider how to develop these pluripotent stem cells for purposes of enhancing human knowledge as well as potentially creating profound changes in our health as a world.

Clearly, the supporters of this bill, even the sponsors of the bill, come at the stem cell issue from a variety of different perspectives. I think it is important to note that

not only does this legislation focus resources in the area of ethical advancements of stem cell research, but that there is also broad support across the spectrum, short-term and long-term, for such a focus.

To close, I would like to provide a brief summary of the Alternative Pluripotent Stem Cell Therapies Enhancement Act (S. 2754). This bill is intended to intensify research into alternative ways of deriving pluripotent stem cells. Study of these cells may lead to improved understanding of or treatments for diseases. Recognizing the ethical issues surrounding embryonic stem cell research and the potential scientific advances that may alleviate these issues, S. 2754 seeks to promote the derivation of pluripotent stem cell lines from alternative sources that do not require the creation of human embryos for research purposes or discarding, destroying, or knowingly harming a human embryo or fetus.

This bill would amend the Public Health Service Act to require NIH to conduct and support basic and applied research to develop techniques for the isolation, derivation, production, or testing of stem cells that have pluripotent or embryonic-like qualities. Specifically, this refers to stem cells that have the capability of producing all or almost all of the cell types of the developing body and that may result in improved understanding of or treatments for diseases and other adverse health conditions. However, recognizing that there are real ethical concerns with research requiring the destruction of a human embryo and seeking to encourage research into alternative ways of deriving these cells, the bill prohibits these funds from being used for techniques or research that derives such cells from a human embryo.

To implement this research, the Secretary of HHS, in consultation with the Director of NIH, will issue guidelines on research under this provision. They will provide guidance concerning:

—The next steps required for additional research, including the determination of the extent to which specific techniques may require additional basic or animal research to ensure that any research involving human cells is consistent with the purpose of the bill.

—Prioritizing research with the greatest potential for near-term clinical benefit.

—Taking into account the techniques outlined by the President's Council on Bioethics and any other techniques and research. This would include variations on altered nuclear transfer, reprogramming of differentiated somatic cells, and other techniques being used to isolate these pluripotent cells.

The bill authorizes for this research such sums as may be necessary for fiscal years 2007 through 2009. S. 2754 requires a yearly report to Congress on the activities being carried out and research being conducted during the fiscal year.

In this bill, the term "human embryo" has the meaning given in the applicable appropriations act. The applicable appropriations act is defined as the appropriations act providing funding for HHS in the fiscal year the research is conducted or supported. If there were no definition in that year's appropriation act, then the applicable appropriations act would be the act of the previous fiscal year.

Recognizing that supporters of the bill come from varying perspectives on the legitimacy of embryonic stem cell research, S. 2754 contains a rule of construction saying that nothing in this bill shall be construed to affect any policy, guideline, or regulation regarding embryonic stem cell research, human cloning by somatic cell nuclear transfer, or any other research not specifically authorized by this section.

Again, the issue of embryonic stem cell research has been fraught with strong passions and sharp disagreements. But this need not be the case. A commitment to curing disease, promoting scientific progress and respect for life are not mutually exclusive. Despite differing opinions on whether taxpayer dollars should be used to support stem cell research that is dependent on the destruction of a human embryo, there is non-controversial common ground on this issue. This bill finds such common ground.

Thank you again for holding this hearing.

Senator SPECTER. I'm here today with two of my partners, and I didn't yield to Senator Harkin for his opening statement. I was thinking about my Pennsylvania partner, not my committee partner. It's nice to work with partners like Rick Santorum and Tom Harkin.

Senator Harkin, I yield to you for an opening statement.

Senator HARKIN. That's okay. I just ask that it be made a part of the record.

[The statement follows:]

PREPARED STATEMENT OF SENATOR TOM HARKIN

No one in Congress has worked harder on the issue of stem cell research than my chairman, Senator Specter.

He called the very first congressional hearing on stem cells back in 1998, and this will be our 18th on this topic since then. And in the past year, Senator Specter has led the effort to bring H.R. 810 up for a vote in the Senate, so we can pass the bill and send it on to the President.

So I hope he knows how much I admire everything he's done to promote stem cell research.

I think he also knows my feelings about the bill we're discussing today, S. 2754, and I hope he will accept my comments on it in the spirit with which I offer them.

The best thing that can be said about this bill is that it does no harm. It doesn't do any good, but it doesn't do any harm. Otherwise, every activity that's authorized in this bill is something that NIH can already do.

In other words, whether this bill becomes law or whether it fails will have absolutely no impact on the progress of stem cell research.

There is one danger to this bill, however. Some opponents of embryonic stem cell research want to use it as a decoy. They're trying to convince people that they should oppose H.R. 810 and support this bill instead.

That would be a tragic blunder. This bill touts the value of alternative methods of deriving stem cells—not one of which has ever been shown to work in humans. Some haven't even worked in animals. Right now, they're just theories. Maybe one day, 10 years from now, one of these methods will pan out. But maybe not.

Are these methods worth examining? Absolutely. I support any ethical means to improve the lives of human beings who are suffering. In fact, Senator Specter and I included language in our appropriations bill last year urging NIH to support research on derivation methods that don't involve the destruction of a human embryo.

But meanwhile, people we love are dying from Parkinson's and ALS. Children are suffering from juvenile diabetes. People are losing the ability to walk due to spinal cord injuries. They don't have 10 years to wait and see if these alternative methods pan out. They need help now.

That's why our focus needs to be on passing H.R. 810, not on this bill.

Senator HARKIN. I just want to say at the opening, I welcome Senator Santorum here today and to this overall debate. He should be here. Everyone should be here. This should be an open, frank discussion, and I believe it has been.

Quite frankly I don't think anyone has worked harder on the issue of stem cell research than Senator Arlen Specter. As he said, he called the first hearing on this in 1998. As you said, this is our 18th hearing that you have had, Mr. Chairman, on this topic. Well, maybe I had a couple, I don't know, but there are 18 that we've had on this. So I know that Senator Specter knows how much I admire everything he has done on this issue.

I have looked at S. 2754, Senator Santorum, and would I be opposed to it? Why would you be opposed to it? I'm not opposed to it. I think the best thing that can be said about it, it does no harm. I don't know that it does anything that isn't already allowed to do, and I will ask Dr. Battey and others about that. As a matter of fact, we have included report language in our bill in the past that urged NIH to support research on derivation methods that don't involve destruction of a human embryo, so that's already there and they can do that.

But the problem I have with the bill is that there are some, I'm not saying Senator Santorum, but some who are opponents of embryonic stem cell research that may want to use this as a decoy, saying, "Well, if you vote for this, then you don't have to support H.R. 810. This is another way of getting at stem cell research, rather than H.R. 810." So it's in that context, Senator Santorum, that I would like to just engage with you if I could, a little bit, on this.

It sounds, Senator Santorum, that we do agree that stem cell research has a lot of potential for easing human suffering and treating diseases. I think we may agree on that.

Senator SANTORUM. I think what I have said is that it's a line of research that I think should be pursued. I'm not sure at this point that we can make a statement that we know of any necessarily known therapies, but that it's a line of research that I think would be helpful to be pursued, and that's why I support this act.

Senator HARKIN. I think we may have testimony this morning, I'm not certain, but I just read recently, Rick, about an experiment at Johns Hopkins. Actually it has happened before, but they had some mice that had spinal cord injuries, and they had taken stem cells, and they had walked again. So this is mice or rats——

Senator SANTORUM. Well, I know——

Senator HARKIN [continuing]. As someone said, we're 99 percent rats. I don't know if they're talking about us as politicians or not, but——

Senator SANTORUM. Speak for yourself on that one.

Senator HARKIN. A generic term.

Senator SANTORUM. Yes, I understand.

Senator HARKIN. I'm sure, then, we would also agree that we need human stem cell lines to do the research. How many stem cell lines have been created using altered nuclear transfer, which is one of the proposed alternative methods that you're promoting in your bill?

Senator SANTORUM. Again, I think the answer, to my knowledge, is none. But my sense is that this is an area, at least according to a lot of research that has come out, new techniques, altered nuclear transfer is one of the techniques mentioned in the President's report, one of the things that would be funded specifically with this legislation.

But what we're seeing is almost, I won't say on a daily basis but certainly at least once a month you're seeing some new technique or some other derivation of pluripotent cells being developed out there, either in the private sector or in the research lab, and we think that this is a very promising area to be explored. We want to make sure that the NIH has a really comprehensive and holistic look at this, and in not just report language but we express clear congressional intent that this is an area that we'd like them to focus on.

Senator HARKIN. So none from that, and how many human stem cell lines have been created using blastomere extraction, which is another of the proposed alternative methods?

Senator SANTORUM. Again, I'm not sure that any of the techniques that have been described here are ones that have produced any kind of stem cell lines to this point.

Senator HARKIN. That's the point.

Senator SANTORUM. The point is that what we've seen in research labs is that the potential exists, and in fact testimony—we had a group of scientists in just 2 weeks ago, you know, Dr. Gromke as well as Dr. Yenish, both of whom were renowned scientists in the area of stem cell research, both saying that they be-

lieve that these alternative techniques have great promise and should be pursued.

So I'm not suggesting that we're there yet, but I think if you would have had—I'm sure when Senator Specter and you had your first hearing, there may not have been any of the advances then that we're talking about now. It's early stages of development of these techniques, and we'll wait and see whether they'll be successful or not.

Senator HARKIN. Well, I guess that's my point. Every other proposed alternative method has produced no stem cells, stem cell lines, but current methods have produced dozens. So my point is, if scientists want to do research with human stem cells, they would have two options. They could use stem cells that are derived from current methods, or they can wait several years for the possibility—and it's just a possibility—that one of the alternative methods will pan out. So it seems to me if you're really interested in promoting stem cell research, it doesn't sound like much of a choice.

Senator SANTORUM. I would say, Senator, that some of the people that have come forward and testified about other methods to develop pluripotent cells have developed those pluripotent cells—I don't know about what you call lines of cells, but have developed pluripotent cells in commercial laboratories using—we have a company in Pittsburgh that testified last week, that takes cells from the lining of the placenta and has been able to transform those cells into a variety of different types of cells that they believe could be useful.

So it's not that cells have not been developed that could potentially be useful. I think there are a lot of alternative methods out there that have developed alternatives to develop these types of, whether muscle cells, nerve cells.

Senator HARKIN. Clearly my point, Senator. Clearly my point. As I said, we have included language. People are looking at these possibilities. I have no problem with that. My problem is that you're going to stop the present embryonic stem cell research using the kind of derivation of stem cell lines that we know works. They have extracted those. They know they can get the pluripotent cells out of these stem cell lines.

So my point is that, you know, we've got people suffering from ALS and juvenile diabetes, and many of the scientists who have testified before us many, many times have said that perhaps the first thing that could be cured using stem cells, embryonic stem cells, would be juvenile diabetes, because of the nature of islet cells and that kind of thing. I don't pretend to even understand all that, but that's what they tell us. I may never.

So I'm just say that if all we're going to tell these people is wait and wait, we're going to examine all these other possibilities, but we're going to clamp down and we're not going to use the kind of stem cell lines that we know can be derived from embryonic stem cells, what kind of hope are you giving these people? All you say is wait.

Senator SANTORUM. I would say, as the Senator knows, if we really want to invest in getting something short term, you would

be doing a lot more investment in adult stem cells than you would in embryonic stem cells.

Senator HARKIN. They're doing that, too.

Senator SANTORUM. Again, I mean, that's the whole point. You make this out to be it's a zero sum game. It's not. It's not a zero sum game. The fact of the matter is that there's research being done on a variety of different areas, and all we're saying is this should be an additional area of research.

Senator HARKIN. But I'm not the one, Senator, trying to stop H.R. 810. You are.

Senator SANTORUM. Senator, I've been very clear about my position on that issue. What we're trying to do here is, I think——

Senator HARKIN. I'm not trying to stop you.

Senator SANTORUM [continuing]. It's pretty clear, Senator, that the chances——

Senator HARKIN. To me it's zero sum.

Senator SANTORUM [continuing]. The chances of that legislation, given a presidential veto, becoming law this year, are not very good. So what I was suggesting is that, since that does not look like a promising approach, that we can at least begin to develop alternatives that may be promising in the future.

Senator HARKIN. Well, one of those alternatives that's being talked about a lot is the altered nuclear transfer. Dr. Hurlbut has testified before us. I've talked to him about it. What you do is, you take normal human DNA, you knock out a gene, you transfer it to a human egg, you create some new human material that no one has ever seen before. It's preprogrammed to die.

I'm surprised that, given your pro life stance on most issues, you support the idea of creating some kind of inherently defective human entity that's destined to die after just a few days. What am I missing here?

Senator SANTORUM. Yes. You're missing that we're not creating a human entity. What we're creating is tissue. We're not creating any type of living organism that could ever be human. So I think a lot of ethicists, bioethicists, have looked at this. There is, I won't say a unanimous feeling, but as broad a consensus as I've seen in the area of bioethics that we are not creating a defective embryo. We are creating something that could not be human, that is not anything but tissue.

Senator HARKIN. Help me explain this. You have a human egg. The DNA inside the egg is human, so you have a human egg, human DNA. So it's not a pig, it's not a rock. What is it? You've got two human things: human DNA, human egg. What is it?

Senator SANTORUM. My understanding is—and probably the scientists will do a little better job at explaining this than I do. I'm not a bioethicist, nor am I a biologist. The reading that I've done and the testimony that I've received from those who are experts, the consensus was that we are not creating an embryo. I am satisfied that, given the testimony that I've received near unanimously, that this is not a human embryo.

Senator HARKIN. Well, I've heard others describe it as a human embryo preprogrammed to die, a defective, an inherently human created defective embryo preprogrammed to die. Because it is an embryo. It's DNA, it's human DNA, it's a human egg.

Senator SANTORUM. I would suggest, Senator, that if that were the case, then I would not be supporting it, the Catholic Conference wouldn't be supporting it, the National Right to Life wouldn't be supporting it, and every other organization that opposes embryonic stem cell research wouldn't be supporting this if that's in fact technically what was going on.

Senator HARKIN. Well, I would quote perhaps one of your favorite columnists—perhaps, I don't know—Charles Krauthammer, who is a member of the President's Council on Bioethics. He described this proposal as being "repugnant" and "weird." I quote him as saying, "It's an aborted attempt to produce a human. It's an attempt to produce a human that went wrong." So that's one member of the President's Bioethics Council——

Senator SANTORUM. You know, there's a variety of opinions out there. I can tell you what the consensus of opinion is, and I'm comfortable with that. Again, that's only one type of research that's being funded under this legislation. That would be one, and probably one of the more speculative ones at that.

Senator HARKIN. Now, I just want to make sure that I heard you correctly. You said the U.S. Catholic Conference supports altered nuclear transfer and says it's ethical?

Senator SANTORUM. My understanding is that they have taken a position in support of this legislation, and since——

Senator HARKIN. I'm not talking about the legislation. I'm talking about altered nuclear transfer.

Senator SANTORUM. I can't imagine—the answer is that they support the legislation that calls for the funding of that, and so I would suspect that they would not have any moral objections to it.

Dr. Yenish, who testified last week, who has done research in this area, said that this is not an embryo. In fact, all the scientists last week that came forward said that this is not an embryo, and as you know from the legislation, this only approves studies in animals, not humans, in order to determine, first, to make sure that we are not creating an embryo.

Senator HARKIN. We got a letter from Dr. Yenish, from the Whitehead Institute, said that he had participated in a recent press conference sponsored by Senator Rick Santorum on his bill, S. 2754. He said, "I'd like to take a moment to clarify my position on his bill and on this complex issue." He said, "S. 2754 should not be viewed as an alternative to pending legislation." Then at the bottom he said, "I strongly back H.R. 810."

Senator SANTORUM. He made that clear in the—

Senator HARKIN. Ok. I just want to make sure that the record shows that. What I have said about your bill, I don't mind this bill. It's fine. I'm just saying I don't know what it does that they can't already do, and the point I'm trying to make is that with H.R. 810, and you might say, "Well, the President will veto it," I don't know if he will or not.

Senator SANTORUM. He has made it pretty clear that he will.

Senator HARKIN. I don't know. He doesn't have it in front of him. I think our job is to do what we can to promote good scientific research and to do it in an ethical manner, which I believe H.R. 810 does, and to get it to the President.

I know our time is short. I don't want to take any more time. I just have one other question I want cleared up for me and for the record, and I just want to understand this: Senator Santorum, do you support in vitro fertilization?

Senator SANTORUM. Do I support in vitro fertilization, as far as whether it should be legal or not, or would I personally do it?

Senator HARKIN. No. First, should it be legal?

Senator SANTORUM. It is legal. I would personally not do it. That's not something that—according to the Catholic faith that I subscribe to, it is against it, and so personally I would not do it, but I would not vote for any law that would outlaw it.

Senator HARKIN. So it's okay if others use in vitro fertilization?

Senator SANTORUM. As you know, it is permissible. I have said I do have concerns about the lack of regulation over in vitro fertilization clinics, and have expressed concerns about that, particularly the number of embryos that are created at a time. I think that's a concern of mine, and I have publicly expressed concern about that, but I have not—I would certainly allow, not vote for any law that would ban in vitro fertilization.

Senator HARKIN. Or restrict it?

Senator SANTORUM. Well, again, my concerns, I do have concerns about the number of embryos created in certain circumstances in in-vitro clinics, and so when you say "not restrict it," it would depend. I have very serious concern, particularly now that we're getting into potentially embryonic stem cells, that we would be creating a large number of embryos that would never have a chance of being implanted, and so I do have concerns about that.

Senator HARKIN. I think H.R. 810 just speaks about the embryos that have already been created, which are about 400,000.

Senator SANTORUM. I understand that, but that's now. I mean, there's always the future, and I have concerns about that.

Senator HARKIN. Well, it just seems to me we may have a difference on this. It just seems that if in vitro fertilization is legal and you say it's fine and you wouldn't end it, you would let it go, and we have all these leftover embryos that are frozen, that can be used to derive stem cells that scientists tell us can be used to help cure some very serious illnesses, I don't know what you do with 400,000 embryos. I mean, they're being discarded every day, right now.

I mean, you look upon this as morally repugnant, but it seems to me that the best use would be to say if you can use these to help sustain life and to ease suffering and pain, that that would be the morally right thing to do, rather than to have them discarded. That seems to me to be what H.R. 810 is trying to do.

Senator SANTORUM. I understand that, and as I said in my opening remarks, I think people of good conscience can be on both sides of this issue. I happen to believe that that is not the better moral choice; that the better moral choice would be to let that individual, and the embryo is an individual, it's human life, to die with dignity as opposed to being used for research purposes without their consent. That's the moral choice that I have made. I disagree with you. You disagree with me. I respect your opinion.

Senator HARKIN. It seems to me than an embryo, to die with dignity, getting flushed down a toilet like they do now is not dignity.

But to extract stem cell lines and to use it to promote and enhance life, to me is dying with dignity.

Senator SANTORUM. We disagree.

Senator HARKIN. That's our difference.

Senator SANTORUM. Thank you.

Senator SPECTER. Thank you very much, Senator Harkin.

Thank you, Senator Santorum.

We now turn to our second panel. I renew the invitation to Senator Santorum to join us on the panel. Our first witness is Dr. James Battey, Chairman of the NIH Stem Cell Task Force, Director of the National Institute on Deafness and Other Communication Disorders at NIH. Bachelor of Science from California Institute of Technology, and M.D. and Ph.D. degrees from Stanford.

Thank you for joining us again today, Dr. Battey. As you know, our practice is to have 5-minute rounds. We want to invite Dr. Alan Leshner and Dr. Stephen Strom to join us on the panel at this time, and the floor is yours, Dr. Battey, for 5 minutes.

STATEMENT OF JAMES F. BATTEY, JR., M.D., Ph.D., DIRECTOR, NATIONAL INSTITUTE ON DEAFNESS AND OTHER COMMUNICATION DISORDERS, AND CHAIR, NIH STEM CELL TASK FORCE, NATIONAL INSTITUTES OF HEALTH, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Dr. BATTEY. Mr. Chairman, Senator Harkin, and other distinguished members of the subcommittee, I am delighted to have an opportunity to again testify about stem cell research. I've had an opportunity on several other occasions to do so, and I'm sure you are aware that I believe human embryonic stem cells are an important tool for advancing our knowledge about cell specialization, and it has great potential to ultimately be medically valuable and beneficial.

However, as I'm sure the last 25 minutes have highlighted, there are differences of opinion about the moral and ethical wisdom of destroying human embryos for the purpose of creating pluripotent cells. There have been recent publications describing potentially alternative ways to establish human pluripotent stem cells that claim to avoid the contentious issue of creating, destroying, or harming human embryos, and I'm going to try to quickly outline a little bit about the science and what the state of the science is in this area.

So I'm going to begin by talking about pluripotent stem cells from nonviable embryos. Scientists proposing this method noted that during human in vitro fertilization or IVF, that there are numerous embryos that fail to continue to divide and are judged to be unsuitable for implantation.

They argue that these nondividing entities are dead, and they propose that harvesting cells from these embryos for the purpose of creating a human embryonic stem cell line is no different than organ donation by a person judged to be brain dead. They argue that this approach is morally acceptable.

Recently these same scientists published a paper where they evaluated the physical characteristics of human embryos created for IVF but not used because they were considered to be nonviable.

They observed that some of the nonviable embryos had fewer cells than would be expected otherwise, and that they failed to

compact and clump together into a structure called a morula, which is typically during normal human development what is happening around 4 days postfertilization, or a blastocyst, which is the structure that we typically have 5 days after fertilization. They proposed that these nonviable embryos with these features of arrested development at 5 days postfertilization be considered dead, and might serve as an acceptable source of nonviable human embryos in an attempt to generate human embryonic stem cell lines.

From a scientific perspective, there is no published study showing that it is possible to generate an embryonic stem cell line from a nondividing embryo fulfilling these criteria, in rodents, nonhuman primates, or humans. If stem cell lines could be derived from such embryos, the resulting cell line would have to be carefully monitored for genetic abnormalities or other defects which could be the underlying cause of the embryo's failure to develop in the first place.

Finally, the human embryo research ban to the Department of Health and Human Services appropriation act prohibits the use of funds appropriated to DHHS to support the creation of a human embryo for research purposes, or research in which a human embryo is destroyed, discarded, or subjected to risk of injury or death greater than that allowed under Federal requirements for fetuses in utero. Applicability of this prohibition would have to be analyzed before NIH could fund research on this technique using human embryos.

Now I would like to turn to pluripotent stem cells from biopsied blastomeres. This proposal involves creating an embryonic stem cell line by removing a cell from an embryo at the eight-cell stage, which is typically 3 days postfertilization in an IVF clinic, and it's referred to as single cell embryo biopsy.

A similar procedure is already in use for preimplantation genetic diagnosis, where a single cell is removed from an eight-cell stage embryo for genetic analysis. The remaining seven cells, constituting the embryo, are used for reproductive purposes through the standard IVF procedure, if the genetic analysis of that single cell shows the embryo to be genetically healthy.

The proponents of this proposal suggest that the success of preimplantation genetic diagnosis is proof of principle that removal of a single cell does not frequently damage the remaining embryo. Using this premise, this proposal argues that a single cell or several cells may be removed from an embryo at the eight-cell stage at the same time the embryo is undergoing preimplantation genetic diagnosis, and that these additional cells could be used for the purpose of creating a human embryonic stem cell line.

The proposal further argues that if one limits this approach to embryos undergoing preimplantation genetic diagnosis, one is not compromising any embryos that are not already being compromised, and is assured that embryos that are being used for this purpose were created for reproductive purposes and not solely for research purposes.

Recently, privately funded scientists attempted to establish a mouse embryonic stem cell line using this procedure, single cell embryo biopsy. After harvesting a single cell, and attempts to establish a mouse ES cell line, the remaining cells of the embryo

were implanted in surrogate mouse wombs, and approximately half of these embryos developed into seemingly normal mouse pups, and that's about the same percentage as in the control group where the embryos were not biopsied.

So this research is the first to demonstrate that single cell embryo biopsy can be used successfully to generate stem cell lines in a mouse model organism. If the technique succeeds with human embryos, it may provide another way to generate human embryonic stem cell lines.

But it's important to note that scientists do not yet know how much risk the procedure actually might confer to an otherwise healthy human embryo. Additionally, these experiments do not address the concern that the very early cell that is biopsied and used for PGD may in itself be capable of developing into a living human being, and if this were true, destruction of the single cell may——

Senator SPECTER. Dr. Battey, how much longer would you need for your statement?

Dr. BATTEY. I can cut right to the end and just take your questions.

Senator SPECTER. Would you please do that?

Dr. BATTEY. I will do that, and I'm sorry that I've gone over my time.

Senator SPECTER. That's okay.

PREPARED STATEMENT

Dr. BATTEY. We welcome the receipt of investigator-initiated research grant applications whose goal is to generate pluripotent cells using technology that does not require the use of potentially viable embryos, so long as this research is not judged to be ineligible for Federal funding because of the human embryo research ban.

Senator SPECTER. Thank you very much, Dr. Battey.

[The statement follows:]

PREPARED STATEMENT OF DR. JAMES F. BATTEY

Mr. Chairman, Senator Harkin, and Members of the Subcommittee, I am pleased to appear before you today to testify about stem cell research. As you are aware, I previously testified to this Subcommittee about human embryonic stem cells (hESC) as a tool for advancing our knowledge about cell specialization, and its great potential to be medically valuable. However, using established methods, these cannot be obtained without destroying human embryos. There have been recent publications about alternative ways to establish human pluripotent stem cell lines that claim to avoid the issue of creating, destroying, or harming human embryos. In 2005, the President's Council on Bioethics published a white paper on "Alternative Sources of Human Pluripotent Stem Cells." My testimony will provide some information on the scientific advances highlighted in that report.

PLURIPOTENT STEM CELLS FROM NONVIABLE EMBRYOS

Scientists proposing this method noted that during the human in vitro fertilization (IVF) process, there are numerous embryos that fail to continue to divide and are therefore judged to be unsuitable for implantation.

Recently, in a privately funded study, the scientists evaluated the physical characteristics of human embryos created for IVF but not used because they were considered to be "nonviable." The scientists observed that many of the nonviable embryos had fewer cells than normal, and failed to compact into a morula or a blastocyst, which are developmental stages of the embryo. They propose that nonviable embryos with these features of arrested development at 5 days post-feritilization be considered "dead." This would allow scientists to harvest cells from nonviable

human embryos in experimental efforts to generate human embryonic stem cell lines. (Regen. Med. 1: 367–371, D.W. Landry, H.A. Zucker, M.V. Sauer, M. Reznik, L. Wiebe).

To date, there is no published study showing that it is possible to generate an embryonic stem cell line from a non-dividing embryo in rodents, non-human primates, or humans. If stem cell lines could be derived from such embryos, the resulting cell line would have to be carefully monitored for karyotypic (genetic) abnormalities or other defects.

PLURIPOTENT STEM CELLS FROM BIOPSIED BLASTOMERES

This proposal involves creating an embryonic stem cell line by using a blastomere cell from an embryo. When performing pre-implantation genetic diagnosis (PGD), a single blastomere cell is removed from an 8-cell stage embryo (approximately day 3 in embryo development where all cells are assumed to be totipotent) for genetic analysis, and the remaining seven cells constituting the embryo are used for reproductive purposes through the standard IVF procedure. The proposal states that a single cell, or several cells, might be removed from an embryo at the 8-cell stage at the same time the embryo is undergoing PGD, and these additional cell(s) could be used for the purpose of creating a hESC line.

Recently, privately funded scientists removed (i.e., biopsied) single cells from early mouse embryos and used them to establish mouse embryonic stem cell lines. The remaining cells of the embryo were implanted in surrogate mouse wombs, and approximately half developed into seemingly normal mouse pups. In the control group of embryos that did not undergo biopsies, about half also developed to birth as normal pups. This research is the first to demonstrate that single cell embryo biopsy can be used successfully to generate stem cell lines. If this technique succeeds with human embryos, it may provide another way to generate human embryonic stem cell lines. Although single cell embryo biopsy proposes to avoid embryo destruction, scientists do not yet know how much risk the procedure might confer to an otherwise healthy human embryo. (*Nature* 439:216–219, laboratory of R. Lanza)

NIH believes that such experiments could and should be pursued in non-human primates. If this approach is successful, the resulting stem cell lines would, of course, have to be validated for genetic stability, pluripotency, and unlimited self-renewal—all cardinal features of embryonic stem cell lines generated from blastocysts by culturing the inner cell mass.

PLURIPOTENT STEM CELLS FROM BIOLOGICAL ARTIFACTS

Proponents of this method assert that it may be possible to do the following: (1) genetically modify a somatic cell in culture, for instance, the cell might be engineered to lack a gene or genes crucial for cell-to-cell signaling or the integrated organization essential for normal embryogenesis; (2) use this genetically modified somatic cell as the source of a nucleus and genome for somatic cell nuclear transfer (SCNT) into a human oocyte. This method is referred to as Altered Nuclear Transfer (ANT); (3) allow the resulting entity to develop to a point when it may yield embryonic-like stem cells; and (4) after extraction, attempt to generate a hESC or hESC-like line from these cells.

ANT is a general concept that its proponents suggest could take a number of specific forms. One version of the idea proposes that scientists turn off a gene needed for implantation in the uterus (*Cdx2*) in the patient cell nucleus before it is transferred into the donor egg. NIH-supported scientists recently reported proof of principle tests that ANT works in mice. Mouse ANT entities whose *Cdx2* gene is switched off are unable to implant in the uterus and do not survive to birth. However, scientists used ANT to create viable stem cell lines capable of producing almost all cell types. The scientists point out that this technique must still be tested with monkey and human donor nuclei, and the manipulation needed to control *Cdx2* expression introduces another logistical hurdle that may complicate ANT's use to derive embryonic stem cells. (*Nature* 439(7073):212–5, laboratory of R. Jaenisch)

PLURIPOTENT STEM CELLS BY REPROGRAMMING SOMATIC CELLS

This proposal involves reprogramming human somatic cells, perhaps with the aid of special cytoplasmic factors obtained from oocytes (or from pluripotent embryonic stem cells), so as to "dedifferentiate" them back into pluripotent stem cells. Crucial to this approach is discovering a way to reverse cell differentiation all the way back to pluripotency, but not further back to totipotency.

Scientists in Germany recently succeeded in coaxing adult mouse stem cells that normally produce sperm (spermatogonial stem cells, or SSCs) to instead behave in a manner similar to embryonic stem cells. They accomplished this switch of fate by

finding the elusive SSCs in mouse testicles and growing them in the laboratory under standard embryonic stem cell culture conditions. Under those conditions, the cells made several proteins characteristic of embryonic stem cells. The scientists subjected the cells to critical tests for pluripotency, and their results suggest that the cells can become any type of cell in the body. As a result, the scientists named them multipotent adult germline stem cells (maGSCs). If scientists can find similar cells in human testicles, the cells could provide a new source of patient-specific stem cells, and could also provide more pluripotent cell lines for research. (*Nature* advance online publication, laboratory of G. Hasenfuss)

In another study, privately funded scientists fused cultured adult human skin cells with hESCs. The resulting "hybrid" cells had many characteristics of hESCs—they grew and divided in a similar manner and manufactured proteins that are typically made in hESCs. Some as-yet unknown factor(s) within the hESCs enabled them to "reprogram" the adult skin cells to behave as hESCs. The cells still raise a significant technical barrier that must be overcome before they can be used to treat patients. Because fused cells are tetraploid (i.e., they contain four copies of the cellular DNA rather than the normal two copies), scientists must develop a method to remove the extra DNA without eliminating their hESC-like properties. If this hurdle can be overcome, this technique may one day allow scientists to create patient-specific stem cells without using human eggs. At present, this new approach to creating stem cells is a useful model system for studying how stem cells "reprogram" adult cells to have properties of pluripotent cells. (*Science* 309:1369–1373, laboratory of K. Eggan)

Privately funded scientists in the United Kingdom now report that the reprogramming process in mice is more efficient when they engineer the stem cells to overexpress *Nanog*, a gene important for maintaining stem cells' self-renewing properties. The scientists reported a 200-fold increase in the efficiency of the process when mouse embryonic stem cells that over-expressed *Nanog* were fused with stem cells from mouse brain; however, the fused cells are tetraploid. This study demonstrates that *Nanog* plays an important role in reprogramming the mouse brain cells to a state of pluripotency. If these results can be repeated with human cells, they would represent a first step toward learning how to reprogram adult cells to behave as stem cells and directing them to become specific cell types for use in treating human beings. (*Nature* Advance Online Publication 14 June 2006; lab of A. Smith)

CONCLUSION

NIH welcomes the receipt of investigator-initiated grant applications on these research topics. As with all grant applications, such proposals would be judged for scientific merit by peer review. We are very grateful for your continued support. I will be happy to try to answer any questions that you might have.

STATEMENT OF ALAN I. LESHNER, Ph.D., CHIEF EXECUTIVE OFFICER, AMERICAN ASSOCIATION FOR THE ADVANCEMENT OF SCIENCE

Senator SPECTER. Our next witness is Dr. Alan Leshner, chief executive officer of the American Association for the Advancement of Science and executive publisher of the Science magazine. Prior to joining the association, Dr. Leshner was Director of the National Institute on Drug Abuse at NIH. Undergraduate degree from Franklin Marshall, Master of Science and Ph.D. from Rutgers.

Thank you for coming in today, Dr. Leshner, and the floor is yours.

Dr. LESHNER. Thank you very much, Senators. I'm delighted to be here to testify on behalf of AAAS, which is the world's largest multiple-discipline scientific society, and as you said, publisher of the journal Science. AAAS was founded in 1848, and includes some 262 affiliated societies that, in the aggregate, represent roughly 10 million individuals around the world.

Let me start by saying that we loudly applaud your efforts, Senators, in holding this hearing today and in your other significant work on the issue of stem cell research and its tremendous clinical promise. We believe that the great clinical promise in stem cells

makes it critically important to support research on a wide range of approaches toward deriving cells that have the potential for replacing damaged or deteriorating parts of the body.

I can say that since the breakthrough in human embryonic stem cell research in 1998, an overwhelming majority of the scientific community and as well a significant proportion of the American people have held the position that only through Federal support of research on both adult and embryonic stem cells can we understand fully the potential value and the limitations of stem cells as an eventual clinical application for a wide variety of illnesses.

The AAAS board of directors formalized its position in 2002 with a resolution that strongly endorsed embryonic stem cell research techniques, including nuclear transplantation, and called for a ban on reproductive cloning. At the same time our board emphasized this research should only proceed if it's guided by clear ethical guidelines.

In that regard, in 2005 the National Academies issued its guidelines for human embryonic stem cell research. These guidelines were prepared to enhance the integrity of human embryonic stem cell research by encouraging responsible practices and they address the wide array of ethical, legal, scientific, and policy issues.

As the bill under discussion makes clear, we're now seeing a variety of new techniques that appear to hold some potential as additional routes for deriving stem cells. We at AAAS encourage research into these approaches, although they are still in very early stages of development, as you have heard this morning.

The alternatives that are now being developed are in fact intriguing, but we really don't know what their ultimate utility will be, and each has potential problems or complications that will require a great deal more research before we know what their viability might be. This entire field is still very young, and at the moment we believe the most promising method appears to be the derivation of embryonic stem cells, either through somatic cell nuclear transfer or from excess embryos from in vitro fertilization clinics.

As you mentioned before, as just one example, within the past 2 weeks Johns Hopkins University revealed that a team of researchers had utilized injections of embryonic stem cells into rat spinal cords to rewire part of their nervous systems and restore muscle function, the ability to walk.

I do want to mention that the embryonic stem cell issue has more than just clinical implications. Many of the countries with whom we cooperate and compete, both scientifically and economically, are intensively pursuing human embryonic stem cell research. Countries like Great Britain, Singapore, South Korea, Israel, those in Scandinavia, have very advanced programs in human embryonic stem cell research.

On June 15 the European Union parliament in effect approved funding human embryonic stem cell research as part of their Framework 7 research program. Several prominent U.S. scientists have already taken their research abroad.

Moreover, many States in this country, impatient with current Federal policies, have developed their own research support mechanisms so that their scientists will not be left behind competitors in other countries. This will better enable those States to reap the

eventual benefits of locally conducted human embryonic stem cell research.

PREPARED STATEMENT

In closing, I want to congratulate you again for shining a bright light on this field of stem cell research that has such tremendous potential health and economic benefits for the people of this country, and I hope that we will do all we can to ensure that the full range of approaches are studied to their scientific and ethical limits. Thank you.

Senator SPECTER. Thank you very much, Dr. Leshner.

[The statement follows:]

PREPARED STATEMENT OF DR. ALAN I. LESHNER

I am very pleased to appear before you on behalf of the American Association for the Advancement of Science (AAAS), the world's largest multiple discipline scientific society and publisher of the journal, *Science* (www.sciencemag.org). AAAS was founded in 1848, and includes some 262 affiliated societies and academies of science, representing roughly 10 million individuals.

We applaud both your efforts, Senator Specter and Senator Santorum, in holding this hearing today. We hope it will draw more attention to the importance of research focused on developing and making use of stem cells derived in a variety of ways. We believe that the great clinical promise in stem cells makes it critically important to support research on a wide range of approaches toward deriving cells that have the potential for replacing damaged or deteriorating parts of the body.

Since the breakthrough in human embryonic stem cell research in 1998, a large majority of the scientific community, and, I might add, a significant proportion of the American people, have held the position that only through federal support of research on both adult and embryonic stem cells can we understand fully the potential value and limitations of stem cells as an eventual clinical application for a wide variety of illnesses. The AAAS Board formalized its position in a 2002 resolution that strongly endorsed embryonic stem cell research, including nuclear transplantation techniques, and called for a ban on reproductive cloning. At the same time, the Board emphasized that this research should only proceed if it is guided by clear ethical guidelines that protect patients and build public confidence. In 2005, the National Academies issued its Guidelines for Human Embryonic Stem Cell Research. These guidelines were prepared to enhance the integrity of human embryonic stem cell research by encouraging responsible practices in the conduct of that research. They address the many ethical, legal, scientific, and policy issues that concern both scientists and the public.

As S. 2754 makes clear, we are now seeing a variety of new techniques that appear to hold potential as additional routes for deriving stem cells. We support research into these approaches, although they are still in early stages of development. The alternatives that are now being developed are intriguing, but we really do not know what their ultimate utility will be. Moreover, as these new techniques are being explored, and they should be, ethical questions will arise. This reinforces our belief that public research policies should not be driven by any single approach.

The entire field is still very young, and at the moment the most promising method appears to be the derivation of embryonic stem cells, either through somatic cell nuclear transfer or from excess embryos from in-vitro fertilization clinics. As just one example, within the past 2 weeks, the Johns Hopkins University revealed that a team of researchers, with the support of NIH and the Muscular Dystrophy Association, had utilized injections of embryonic stem cells into rats to rewire part of their nervous systems and restore muscle function and the ability to walk.

The embryonic stem cell issue has more than just clinical implications. Many of the countries with whom we cooperate and compete, both scientifically and economically, are intensively pursuing human embryonic stem cell research. Countries like Great Britain, Singapore, South Korea, Israel, and those in Scandinavia have very advanced programs in human embryonic stem cell research. On June 15, the European Union Parliament in effect approved funding human embryonic stem cell research as a part of their Framework 7 research program. Several prominent U.S. scientists have already taken their research abroad.

Moreover, many states in this county, impatient with current Federal policies, have developed their own research support mechanisms so that their scientists will

not be left behind competitors in other countries. This will better enable those states to reap the eventual benefits of locally conducted human embryonic stem cell research.

In closing, I want to congratulate you again for shining a bright light on this field of stem cell research that has such tremendous potential health and economic benefits for the people of this country. I hope we will do all we can to ensure that the full range of approaches are studied to their scientific and ethical limits.

STATEMENT OF STEPHEN STROM, Ph.D., PROFESSOR, DEPARTMENT OF PATHOLOGY, UNIVERSITY OF PITTSBURGH

Senator SPECTER. Our final witness on the panel is Dr. Stephen Strom, professor at the University of Pittsburgh. Undergraduate degree from Westmore College in Lamar, Iowa, so that he's a twofer, both Iowa and Pennsylvania. We don't often get that. We thank you, Dr. Strom. Ph.D. at the University of Kansas Medical Center. Pardon me, you're a threefer, because my home State is Kansas.

Do you have anything else to recommend you, Dr. Strom, before we turn to you? Thank you for being with us and for representing Pennsylvania, Iowa, and Kansas. The floor is yours.

Dr. STROM. Good morning, Senator Specter. Senator Harkin, it's a pleasure to meet you, as well, and Senator Santorum. Thank you for inviting me to talk about our research today.

Our laboratory has been involved in the area of regenerative medicine for over 15 years. We believe that many liver diseases can be treated by transplantation of isolated liver cells, not just by organ transplant alone, but actually by transplantation of isolated liver cells into these patients.

Our group was the first in the United States to treat liver failure and metabolic liver disease by the transplantation of isolated hepatocytes. We have actually transplanted about 25 patients to date, and the results, although still experimental, are quite promising, so this regenerative medicine approach actually works.

Just as with whole organ transplants, there is a problem with the cell source, so a number of years ago we became somewhat reluctant stem cell biologists. We tried to generate liver cells for these transplant procedures through different mechanisms from stem cells.

Again, for a number of reasons we decided to focus on the placenta as a possible stem cell source. We began to look for cells that had characteristics of embryonic stem cells, and we were surprised and clearly gratified to find that there's a number of stem cell characteristics that can be found on the amniotic epithelial cells.

So late in November of last year we reported that the amniotic epithelial cells isolated from human term placentas expressed the surface markers normally present on embryonic stem cells, including the stage specific embryonic antigens and the tumor rejection antigens. In addition, they expressed the genes that are thought to be the molecular basis of pluripotency, including nanog and Oct-4.

Based on immunological data, we were able to demonstrate that these cells can differentiate to all three germ layers in a culture dish, and that includes endodermal differentiation such as liver and pancreas, mesodermal differentiation such as cardiomyocytes, and ectodermal differentiation into neural cells such as neurons and neuroglia. Under specific conditions, we can even get some self-renewal of these stem cells.

We believe this stem cell source from human amnion has several characteristics which will be very useful for transplantation and regenerative medicine. First of all, these cells appear to be pluripotent, and they can form all the cell types of the body. The amnion does not require feeder layers, so they could be grown without exogenous feeder layers and the problems associated with that.

The amnion-derived stem cells do not form tumors when transplanted into animals, and they have even been transplanted into humans already in other types of research, and they are not tumorigenic in humans.

The amnion is freely available, and it is discarded, it is normally thrown away after a live birth of a baby, so therefore it's almost like throwing the baby out with the bath water. We believe we're throwing away stem cells every day, when we could be saving these.

Amnion is certainly abundantly available in the United States. With over 4 million live births, there's going to be a number of HLA phenotypes that are available to actually match virtually every patient that would need a transplant in the United States. Amnion-derived stem cells are obtained from a term placenta, and this is only available to us after a live birth of a baby, so thus we believe that there will be no social, ethical, or religious opposition to the use of this stem cell source.

PREPARED STATEMENT

I would like to conclude from our initial studies that these cells may be a very useful stem cell source for transplantation and regenerative medicine, and we urge support from the Congress on this promising area. Thank you.

Senator SPECTER. Thank you very much, Dr. Strom.

[The statement follows:]

PREPARED STATEMENT OF DR. STEPHEN STROM

STEM CELL CHARACTERISTICS OF AMNIOTIC EPITHELIAL CELLS

Good morning, Senator Specter and other Members of the Senate Labor/Health and Human Services/Education and Related Agencies Appropriations Subcommittee. My name is Dr. Stephen Strom, and I am a professor in the Department of Pathology in the School of Medicine at the University of Pittsburgh. I am also affiliated with the McGowan Institute for Regenerative Medicine at the University of Pittsburgh. I am pleased to have the opportunity this morning to provide testimony on my research on amniotic epithelial cells, as a scientifically appropriate and non-controversial alternative to embryonic stem cells for cell transplantation and regenerative medicine.

Our laboratory has been active in the area of regenerative medicine for nearly 15 years. We believe that some liver diseases currently treated by whole organ transplantation might be corrected, by the transplantation of isolated liver cells in a procedure which is simple, safe, less invasive and less costly than whole organ transplantation. We were the first group in the United States to treat liver failure and metabolic liver disease by the transplantation of isolated liver cells. So far our group has treated approximately 25 patients with this cellular therapy. While still experimental, the results suggest that liver cell transplants can support life in patients with terminal liver failure and correct metabolic diseases of the liver.[1]

Just as with whole organ transplants, there is a shortage of donor livers for liver cell isolation. Approximately 3 years ago we became somewhat reluctant stem cell biologists and decided to try to generate liver cells for our transplants from stem

[1] Strom et al., Hepatocyte Transplantation: Clinical experience and potential for future use. Cell Transplantation 15 (Supplement 1) S105–110, 2006.

cells. For a number of reasons we decided to focus on the amnion layer of the placenta as a possible stem cell source. We began to search for cells with characteristics similar to those reported for embryonic stem cells. The results were clear, the amnion of human placenta contains cells with cell surface markers and a gene expression profile which is very similar to those found on embryonic stem cells.

Last November in the journal *Stem Cells,* we reported that amniotic epithelial (AE)[2] cells isolated from human term placenta express surface markers normally present on embryonic stem and germ cells including stage specific embryonic antigens (SSEA) 3 and 4 and Tumor rejection antigens (TRA) 1–60, 1–81. Like embryonic stem cells, amniotic epithelial cells express the genes thought to be the basis of pluripotency including the expression of octamer-binding protein 4 (Oct-4), and nanog. Based on immunohistochemical and genetic analysis, we were able to demonstrate that in a culture dish, amniotic epithelial cells have the potential to differentiate to all three germ layers—endoderm (liver, pancreas), mesoderm (cardiomyocyte), and ectoderm (neural cells). Under specific culture conditions, amniotic epithelial cells display the capacity for self renewal.

We believe that stem cells derived from human amnion display several characteristics that suggest that they will be useful for cell transplantation and regenerative medicine:

1. Amnion expresses markers of pluripotency suggesting that they may have the capacity to become every cell type in the body.
2. Amnion does not require feeder layers for maintenance of the stem cells.
3. Amnion-derived stem cells do not form tumors when transplanted.
4. Amnion is freely available because it is normally discarded following a live birth.
5. Amnion is abundantly available from the over 4 million live births each year in the United States.
6. Amnion-derived stem cells are obtained from term placenta, and only following a live birth of a baby. Thus, we believe that there will be no social, ethical or religious opposition to the use of stem cells from this source.

My colleagues and I conclude from our initial studies that amnion derived stem cells may be a useful and non-controversial source of stem cells for cell transplantation and regenerative medicine. We urge the United States Congress to support this promising area of research in every way possible. Thank you.

Senator SPECTER. We'll now begin the 5-minute rounds of questions by panelists. Dr. Leshner, I understood you to testify that you think embryonic stem cell research has the greatest potential?

Dr. LESHNER. Yes, sir, I do. On the basis of the research that has been done so far, we see that embryonic stem cells appear to be——

Senator SPECTER. Would you like to see the restriction on Federal funding eliminated, so that Federal funds in NIH could be used on embryonic stem cells?

Dr. LESHNER. Absolutely, sir.

Senator SPECTER. But at the same time you see merit in the proposal for embryonic stem cells, for shorthand we call it Specter-Harkin, but you do see the potential for long-range research on what S. 2754 has, denominated Santorum-Specter?

Dr. LESHNER. Absolutely. I would like to see every line pursued, because we know that cells that have the capacity to develop into new organs or to repair damaged tissue are going to have tremendous clinical importance. So I'm in favor of having all lines of research supported, but I do have to repeat that in particular we believe that embryonic stem cell research right now, at this point, has the greatest promise and needs to be supported.

Senator SPECTER. Dr. Battey, would you concur with that, that it is desirable to use all phases, adult stem cells, cord blood, embryonic, the approach which Senator Santorum has described here,

[2] Miki, et al., Stem Cell Characteristics of amniotic epithelial cells. Stem Cells 23: 1549–1559, 2005.

embodied in S. 2754, known as the Santorum-Specter bill, all should be pursued?

Dr. BATTEY. I think it's impossible at this time to know exactly which source of stem cells will ultimately be most beneficial for a specific clinical application. Given that we're in the very early, basic phase of research, I would support research on stem cells from a wide variety of sources.

Senator SPECTER. Would you concur with Dr. Leshner that based on current information, embryonic stem cells have the best chance, although all others ought to be pursued?

Dr. BATTEY. They have, human embryonic stem cells have two unique properties that differentiate them from stem cells from other sources. They have an unlimited capacity to self-renew in the laboratory, and so far as we know they have the capacity to differentiate into any one of the many hundreds of types of mature cell types. Those two unique properties make them particularly interesting to the scientific community.

Senator SPECTER. Would you say, then, that they're the best available, although all others ought to be pursued?

Dr. BATTEY. I would say, I would concur with the argument that we need to look at all different types of stem cells because we don't yet know which will be the most interesting.

To me, the very most interesting thing, which is on the very far horizon, is this frontier area of nuclear reprogramming, where you take a mature adult cell type and you effectively dedifferentiate it back to a pluripotent state. If we were able to do this, we could make pluripotent cells from adult cell types from a patient and then differentiate those cells into whatever cellular therapy were needed.

So this is, again, an area where we are in the very early stages. We know that nuclear——

Senator SPECTER. So you would just like to have lots of money to work on all these things.

Dr. BATTEY. Yes.

Senator SPECTER. Dr. Strom, have you heard Dr. Leshner or Dr. Battey say anything in response to my questions that you disagree with?

Dr. STROM. Oh, absolutely not. I think we all agree on that.

Senator SPECTER. Well, that's a very good, succinct answer which saves you further questioning.

As I said at the outset, the Judiciary Committee is having a hearing at 10 o'clock which I'm going to have to excuse myself for.

I again want to thank my colleague, Senator Santorum, for his work above and beyond the call of duty. He has a lot of responsibilities in a lot of other fields, but he has taken time to get into this subject very, very deeply, and I can tell you that he's in it very deeply because we had a lot of discussions. We spent a lot of time around the conference table with our staffs to work through the issue and to come up with this legislation.

Before departing and turning over the gavel to Senator Harkin, let me welcome Senator Durbin's arrival and tell him that we'll hold the fort until he gets to the Judiciary Committee. Don't be too long.

Thank you very much, Senator Harkin, for agreeing to take over the chair for the balance of the hearing.

Senator HARKIN [presiding]. Thank you very much, Mr. Chairman, and I'll just use my 5 minutes and then yield to Senator Durbin and Senator Santorum.

Dr. Battey, I guess my question is, and you probably heard the exchange between Senator Santorum and me on S. 2754, I guess my question is, does this bill authorize any new activity that NIH is prohibited from or can't already support?

Dr. BATTEY. The NIH is already in a position to support research on alternative methods for deriving stem cells in animal model systems.

Senator HARKIN. For example, what Dr. Strom is doing with the placenta cells, I mean, that kind of research could be supported by NIH right now?

Dr. BATTEY. As a matter of fact, I believe that the commercial entity with which he is associated has a small business innovation research grant.

Senator HARKIN. So it's being supported?

Dr. BATTEY. I believe that's true.

Senator HARKIN. Is that so, Dr. Strom?

Dr. STROM. I'm actually not part of the company. I really don't know. You would have to ask the company people.

Senator HARKIN. Oh, okay. Well, if you say it is, I'll take your word for it.

So if a researcher applies to NIH for a grant to study an alternative method of deriving stem cells, you would give it the same consideration regardless of whether this bill becomes law?

Dr. BATTEY. It would undergo our peer review process, be judged for scientific merit, and if it received a favorable priority score, would be funded by one of the 27 institutes and centers at NIH.

Senator HARKIN. Let me ask this: Is NIH currently spending more money on human embryonic stem cell research or on human adult stem cell research?

Dr. BATTEY. In 2005 the NIH estimates that it spent about $198 million on human stem cell research where the stem cells come from sources other than the embryo, and in the same fiscal year we estimate that we spent about $38 million on human embryonic stem cell research.

Senator HARKIN. About six times as much on adult stem cells, so it would be true that as a Nation we are not neglecting adult stem cell research, obviously.

Dr. BATTEY. We have no set-aside allowance for either embryonic stem cell research or adult stem cell research. We let the investigator-initiated research grant application process and the peer review process drive the funding. It's driven by scientific excellence as judged by peer review.

Senator HARKIN. Thank you, Dr. Battey.

Dr. Leshner, do you have any more information or can you describe the research just published by scientists at Johns Hopkins, in which embryonic stem cells were used to restore movement in paralyzed mice or rats? I don't know which it was. Do you have any more information on that for us?

Dr. LESHNER. I don't. I just have a copy of a report of it. I have to say I don't even know where it has been or will be published. But it is extremely encouraging, and the technique fits with the expectation you would have of regenerating tissue.

Senator HARKIN. My last question would be this, Dr. Leshner. Is there any scientific merit—I'm just talking about scientific merit, now—to putting all of our hopes for stem cell research on only the alternative methods without pursuing embryonic stem cell research?

Dr. LESHNER. From the point of view of the scientific community that I represent, embryonic stem cell research has tremendous potential and it's critical that it be pursued. My own belief is that it would be a mistake not to pursue it, including using the excess embryos from in vitro fertilization that will be discarded anyway.

Senator HARKIN. I guess my last comment is just that it seems that you pointed out all these countries—Great Britain, Singapore, South Korea, Israel, Scandinavia—all these countries have very advanced embryonic stem cell research programs going on, and I guess I'm not so positioned that we know it all. I mean, there are good scientists in other countries around the world. It would seem to me that if they are pushing hard in that area, it would seem to me that lends some credence, at least some, to saying there is scientific merit—scientific merit—to aggressively pursuing embryonic stem cell research.

Dr. LESHNER. I don't think there is any question in the scientific community about the scientific merit in pursuing embryonic stem cell research.

Senator HARKIN. Thank you very much, Dr. Leshner.

Senator Santorum?

Senator SANTORUM. Thank you, Mr. Chairman.

Dr. Battey, I just want to pick up on something you said that I felt was significant. You said that ultimately what you think would be the optimal is to take adult stem cells and be able to work them back—dedifferentiate; I think was the term you used. Is that correct? Is that the term you used?

Dr. BATTEY. Actually, adult cell types——

Senator SANTORUM. Adult cell types?

Dr. BATTEY [continuing]. Such as fibroblasts. Yes, this is very much now in the pie-in-the-sky category, in terms of our ability to do this in any kind of systematic way. But certainly if it were possible to take adult cell types and to drive the differentiation process backwards so that you made these cells pluripotent, and then could differentiate them into insulin-producing beta islet cells for a child with Type 1 diabetes, then if you began with fibroblasts from that same child, you would have what we call an isogeneic cell, a cell that was genetically perfectly matched.

Now, we are many, many years off, I think, from being able to do this clinically, but I find this is a very exciting area. Dr. Jenisch's name has been mentioned a number of times, and certainly he and Kevin Eggan have active research programs to understand what this nuclear reprogramming is at the molecular level, and NIH is pleased to be able to provide some support for these efforts.

Senator SANTORUM. That would not be considered embryonic stem cell research, right?

Dr. BATTEY. It's research on generating pluripotent cells from adult cell types.

Senator SANTORUM. Right.

Dr. BATTEY. But as I mentioned, there is much, much basic science to be done before we will be able to do this in any systematic way, and I continue to be of the opinion that we need to pursue this avenue of research along with stem cells from a wide variety of sources, so as not to miss any possible opportunity to help patients that are ravaged by these cellular degenerative diseases.

Senator SANTORUM. Agreed, but some have suggested that the only really good, long-term research that we need to be looking at, the real pie-in-the-sky stuff, has to do with embryonic stem cell research, and what you're suggesting is that that's not necessarily the case. There may be, in fact, other types of research that could be even better than that long term.

Dr. BATTEY. Yogi Berra said it best when he said, "Predictions are difficult, especially about the future." When it comes to science, it's very difficult to predict what the state of the science will be in 2020. It's very difficult to predict what the state of the science will be in 2012. So it's dangerous to make predictions, and for that very reason I think——

Senator SANTORUM. It's dangerous to make promises, too, that all these things are going to turn out just the way we hope them to turn out.

Dr. BATTEY. Right, but I think it's fair to say that what we learn in studying how pluripotent cells specialize to become adult cell types stands a very high probability of informing the medicine of the future.

Senator SANTORUM. I agree with that, and as Dr. Strom would say, we have been in very strong support of that, Senator Specter and I both, in funding a lot of that research.

I'm just curious with respect to the adult. I know that you said, when Senator Harkin asked the question about how much adult stem cell research is being done at NIH versus human embryonic. Is that basic adult stem cell research, or is that adult stem cell research that goes to, you know, making bone marrow transplants more efficient? Or is it really, are we really talking about six times more research on basic adult stem cell research, or are you throwing in a lot of other things that you count as stem cell research?

Dr. BATTEY. It's a combination of basic translational and clinical research, and the reason why is that the adult stem cell world, particularly the bone marrow derived hematopoietic stem cells, has been a part of the scientific landscape for many decades, and so——

Senator SANTORUM. Can you differentiate out how much basic adult stem cell research that you're doing, as compared to basic——

Dr. BATTEY. I'm sorry. I don't have those figures with me today. I apologize.

Senator SANTORUM. If you can provide that to me and to the committee, I would appreciate it, if you can do that.

Dr. BATTEY. We'll do the best we can, although in a way you're asking me to draw a line in the sand, because when a research

study goes from being basic to translational is a little like—you know, it certainly could be described as a judgment call.

Senator SANTORUM. I respect that, but I just think it is important for the record to indicate that while one is six times as much as the other, you're talking about a whole variety of different things. Because of the advancement of adult stem cell research in the past, you get into things that are not basic research, and so you're comparing basic research with a whole variety of different research, and it's not necessarily a fair comparison of what NIH is spending their money on.

Dr. BATTEY. I wish we were in a position to begin phase one clinical trials using cells derived from human embryonic stem cells, but we have much to learn before we can do that.

Senator SANTORUM. I'm not arguing that. I just want to make sure that when you make a funding comparison, you're comparing apples to apples, and I think in this case it's not necessarily an apples-to-apples comparison.

So, again, I just thank you for that. I see my time is up, and I appreciate it. Thank you, Mr. Chairman.

Senator HARKIN. Senator Durbin?

Senator DURBIN. Thank you very much, Senator Harkin.

As I listen to this exchange, it reminds me of the movie "Cool Hand Luke," where the fellow said, "What we got here is a basic failure to communicate." We have a panel of real scientists facing a panel of political scientists, and I think maybe we're talking past one another here, so I'd like to get down to some basics.

I understood this hearing was about Senator Santorum's bill that suggested a new avenue of research at NIH and authorizing that research. If anyone here on the real scientist panel has read the Santorum bill, can you tell me whether it authorizes research on stem cells at the NIH that currently is not permissible or legal?

Dr. BATTEY. No, it does not.

Senator DURBIN. Does it expand in any way the opportunities at NIH to do stem cell research?

Dr. BATTEY. We have been in a position to accept a research grant application to study alternative ways for deriving pluripotent cells in animal models for many, many years.

Senator DURBIN. So you already have the authority that is stated in this bill?

Dr. BATTEY. Yes.

Senator DURBIN. What does this bill add, then? I'm sorry Senator Santorum is gone. It apparently doesn't, from your answers, it doesn't add anything to the authority of the National Institutes of Health or our government to do medical research that might be beneficial, so it may have more political science impact than real science impact.

Let me ask you this, if I might. When it comes down to this basic research, the President made an announcement in August 2001 limiting the research on embryonic stem cells. Now, I am a liberal arts major, so please forgive me if I don't get the terminology correct, and correct me. I wouldn't be the least bit embarrassed if you did.

The President limited that embryonic stem cell research to certain existing lines of embryonic stem cells that were then in exist-

ence, but no more. I would like to ask the panel how that has limited our research as a government, that presidential decision, when it comes to embryonic stem cell research.

Dr. BATTEY. From a practical standpoint, a scientist with Federal funding in their laboratory can today order 1 of 21 human embryonic stem cell lines that are eligible for Federal funding, found in locations at various places around the world.

Senator DURBIN. That's it. That's the limitation. Is that correct?

Dr. BATTEY. That's the reality.

Senator DURBIN. So talk to me about the rest of the world that is not encumbered by this decision by President Bush to limit medical research on stem cells. What opportunities do they have that our government scientists, federally funded scientists, do not have?

Dr. BATTEY. Depending on which country you visit, there's a spectrum of science and technology that can be done in other countries, that is not eligible for Federal funding in the United States. Now, let me emphasize "eligible for Federal funding," because the President's policy pertains only to Federal funding. At the Federal level there is absolutely no limitation whatsoever on any of this. It's all legal at the Federal level. Now, some States have passed laws restricting activities within the borders of their State.

Senator DURBIN. Do the other panelists have anything to add or disagree or comment?

Dr. LESHNER. I think an interesting statistic is that in the mid-1990's, I believe as recently as 1998, the United States published over 50 percent of the world's papers annually on stem cells. We now are publishing under 30 percent. So I think there is a very significant danger here that we are ceding the lead in this area of research to other countries.

Senator DURBIN. Well, let me say that I have had several meetings in my State, and I'm sure Senator Harkin has had similar meetings, with people who are praying that this law changes, and quickly. Anyone suffering from disease who wants to keep a hopeful attitude is trusting that their government continues to do medical research which might spare them from juvenile diabetes or Parkinson's or spinal cord injuries, Alzheimer's, Lou Gehrig's disease. The list goes on and on and on. They cannot understand why the United States of America has made a political decision to restrict that research.

We all agree that research, including this research, should have clear ethical guidelines as to how far we can go. We are all opposed to human cloning. I haven't heard a single Member of Congress supporting human cloning. That's not even part of the real discussion here. I think what we have heard from Senator Specter, Senator Harkin, and I would like to join in that chorus, is we are in favor of research, expanding research, finding new cures, within those ethical guidelines.

I came here this morning hoping to find that this bill that is being discussed at this hearing expanded opportunities for medical research. What I have heard from this panel is, it does not. This bill does not add anything to the current authority and ability of our government to do medical research.

My fear, and I think Senator Harkin expressed it earlier, is that some of our colleagues will try to hide behind this bill and say, "If

we endorse this one, then we don't have to face the bill that came over from the House." We're not going to let them off that easily.

We have had a promise from Senator Frist that stem cell research will be called for a vote. We're going to hold him to his promise. He is now in the twilight of his Senate career. He is leaving soon. We have a few months left, and I'm sure he wants to keep his word, and we're going to help him keep his word.

When we return after the 4th of July recess, I think America is finally going to get its wish. We're going to get a vote on stem cell research. I'm glad S. 2754 has been introduced, but it adds nothing to the debate, this important debate.

Thank you, Mr. Chairman.

Senator HARKIN. Thank you, Senator Durbin.

Just in closing, I just wanted to follow up on one that Dr. Battey responded to on the 21 stem cell lines that are available for research. I ask Dr. Battey to confirm or deny what I'm about to say, and that is, I understand that each one of those lines was derived by propagating those lines on mouse feeder cells, and that as such they may be in a contaminated state. In other words, if they have been contaminated by mouse feeder cells, they may never have the possibility of ever being used for human therapies. What we need are stem cells lines that are not derived on mouse feeder cells, but each one of those 21 I guess were. Now, is that correct or not?

Dr. BATTEY. Each of the 21 cell lines that a research scientist with Federal funding can order to do science in their laboratories has been exposed at one point in its history to a mouse feeder cell layer. That is correct.

Senator HARKIN. I just wanted to make that point.

Do any of you have anything else to add to the hearing at all? Going, going——

Dr. STROM. If I might, I mean, I think that the debate on stem cell research has focused in this country almost exclusively on embryonic stem cells, and the thing I wanted to bring to the table today is that there are other stem cells and they also deserve, I think, the interest of the politicians as well as the scientists. So I think we've been in the shade of a very large tree for a long time, and we could use a little sunshine on some of these other stem cell types as well, though.

Senator DURBIN. May I respond?

Senator HARKIN. Sure.

Senator DURBIN. There is no limitation, is there, by policy of this administration or by law?

Senator HARKIN. The only limitation is on embryonic.

Senator DURBIN. That's why we're talking about it.

Dr. STROM. I understand that point, but there is such a focus on a single stem cell. It's like there is no other stem cell. Even in a scientific review committee, if you present something like you are trying to present, they would say, "Well, why are you not doing this also with ES cells?" So I'm just saying that this idea that there is only one stem cell out there is so pervasive that it does block the sun on some other opportunities, I think, and I would just like to keep the mind open.

Senator HARKIN. I would just ask Dr. Leshner, why has there been all this focus on embryonic stem cells, then? It hasn't been from us. It's been from the scientific community, not from us.

Dr. LESHNER. I think that the scientific community sees it at the moment as the most promising approach, but as both of my colleagues have pointed out, there are other approaches. My view is, subject them to peer review, and that's what we have NIH for and that's what we have scientific journals for. As long as alternatives can be supported by NIH and can be published in peer reviewed journals, hear, hear.

CONCLUSION OF HEARING

Senator HARKIN. Thank you all very much for being here. That concludes our hearing.

[Whereupon, at 10:12 a.m., Thursday, June 27, the hearing was concluded, and the subcommittee was recessed, to reconvene subject to the call of the Chair.]

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